



## HerbalGram

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### **FDA Issues Final Rules for Structure/Function Claims for Dietary Supplements Under DSHEA.**

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#### SUMMARY AND BACKGROUND

On January 6, 2000, the Food and Drug Administration (FDA) issued its final regulations on structure/function (SF) claims for dietary supplements (DS) under the Dietary Supplement Health and Education Act of 1994 (DSHEA).(1) The full text is available on the Internet.(2)

These new rules represent a significant shift from those of April 1998(3) when FDA published proposed regulations that included a highly controversial redefinition of the word "disease" in what was viewed by many industry and consumer groups as an attempt to restrict the scope of the SF claims under DSHEA.(4) Since then FDA has received 235,000 comments from the public about this measure: 213,000 as form letters circulated by consumer and trade groups, and 22,000 as individual letters from consumers, members of industry, and other interested parties. In response, FDA held public meetings in July and August 1999 to receive further public comments and extended the comment period for further written comments. FDA's new rules also comment on recommendations made in the report by the White House Commission on Dietary Supplement Labels (CDSL).(5,6)

Of interest to many in the herb industry is the expansion of SF claims to include many conditions previously allowed for over-the-counter (OTC) drugs. FDA has enlarged the range of SF claims by agreeing with the comments by the American Herbal Products Association (AHPA) that some drug claims currently permitted in the OTC drug monographs are not disease claims but are instead claims that deal with the structure or function of the body. Thus, FDA agrees with AHPA that these claims should be allowed for DS as well, without such claims constituting drug labeling. Thus, DS will be able to make claims for antacid, digestive aid, short-term laxative, and other uses previously off limits to DS.

## ANALYSIS OF THE NEW RULES

Definition of Disease. In the new rules FDA has withdrawn its previously proposed definition of disease, which was:

"Any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease." [emphasis added].

Instead, FDA will now use the pre-existing definition of "disease or health-related condition" which was issued as part of the Nutrition Labeling and Health Act of 1990 (NLEA) final regulations on health claims:

"Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such as (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." [emphasis added].

It was this issue of the expansion of the meaning of disease to include conditions that did not constitute damage to the body or an organ that concerned many consumers and industry members, motivating the large number of letters to the agency protesting the proposed definition. Under DSHEA, DS "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" are considered drugs; by proposing to expand the definition of disease, FDA automatically would reduce the range or number of those claims under DSHEA. The final rule lays out a series of disease- or health-related conditions and how they will be regulated. FDA also offers important perspectives on collateral issues, most of which are summarized in the body of this article.

Effect on Disease or Class of Diseases. Under the old proposal, a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a specific disease or class of diseases. FDA included these examples of disease claims: (1) Express Claims: "Protective against the development of cancer"; "reduces the pain and stiffness associated with arthritis"; "decreases the effects of alcohol intoxication"; "alleviates constipation." (2) Implied Claims: "Helps promote urinary tract health"; "helps maintain cardiovascular function and a healthy circulatory system"; "helps maintain intestinal flora"; "promotes relaxation."

In a development that will surely result in new product marketing for herbal products, FDA has stated that certain constipation claims should not be treated as disease claims. Therefore, "For relief of occasional constipation" would not be considered a disease claim. The labeling of a product that claimed to treat occasional constipation should make clear, however, that the product is not intended to be used to treat chronic constipation, which may be a symptom of a serious disease.

Signs or Symptoms of Disease. Under the new rules FDA may look to medical texts and other objective sources of information about disease to determine whether a label implies treatment or prevention of disease by listing the characteristic signs and symptoms of a disease or class of diseases, whether they are printed in technical or lay language. This standard will focus on whether the labeling suggests that the product will produce a change in a set of one or more signs or symptoms characteristic of the disease. Example #1: FDA would not interpret "improves absentmindedness" as implying treatment of Alzheimer's disease, because absentmindedness is not as serious as the type of memory loss usually suffered by Alzheimer's patients. Example #2: FDA believes "inhibits platelet aggregation" is an implied disease treatment/prevention claim. Inhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack and is the mechanism of action of a number of drug products approved for the treatment of stroke and heart attack. Thus, the agency would consider a claim to inhibit normal platelet function to be an implied claim to treat and prevent these disease conditions. Example #3: FDA believes "joint pain" is characteristic of arthritis. The Merck Manual notes joint tenderness as the most sensitive physical sign of rheumatoid arthritis. The claim "helps support cartilage and joint function" is, however, acceptable because it relates to maintaining normal function rather than treating joint pain. Another example: Labeling claiming a product "prevents bone fragility in postmenopausal women" clearly implies that the product prevents osteoporosis and thus is an unacceptable disease claim.

Effects on Abnormal Conditions Associated with a Natural State or Process. FDA believes that many claims concerning the maintenance of "normal" or "healthy" structure or function do not apply to disease prevention in the context of DS labeling unless other statements or pictures in the labeling imply prevention of a specific disease or class of diseases. Statements should not be made that products restore normal or correct abnormal function when the abnormality implies the presence of disease. Example #1: a claim to "restore" normal blood pressure when the abnormality implies hypertension. Example #2: "maintains healthy lungs in smokers" would imply prevention of tobacco-related lung cancer; however, "maintains healthy lung function" alone is an acceptable SF claim. Example #3 deals with a major area of herbal supplements: cholesterol levels. A claim that a DS helps maintain cholesterol levels that are already within the normal range does not necessarily imply disease treatments. FDA has concluded, however, that references to "healthy" cholesterol may be misleading to consumers. FDA continues to believe that "lowered cholesterol," however qualified, is an implied disease claim. FDA will review all cholesterol claims to determine whether the labeling as a whole implies that the product is intended to lower elevated cholesterol levels; in such cases, FDA will consider the labeling to create an implied disease claim. FDA has concluded that an appropriate SF claim for maintaining cholesterol would be, "helps to maintain cholesterol levels that are already within the normal range."

Conditions Associated with Natural States. In its April 1998 notice, FDA had proposed to treat abnormal conditions such as toxemia of pregnancy, premenstrual syndrome, hot flashes, presbyopia, decreased sexual function, and Alzheimer's disease associated with aging as disease states. FDA has reconsidered this position and has concluded that it is

not appropriate under DSHEA to treat certain common non-serious conditions associated with natural states as diseases. There are a wide variety of conditions representing impaired function of an organ or system that are associated with particular states of life or normal physiologic processes, including adolescence, the menstrual cycle, pregnancy, menopause and aging. Thus, mild conditions commonly associated with particular stages of life or normal physiological processes will not be considered diseases. However, a statement will be considered a disease claim if it claims that the product "has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm." Ordinarily, FDA agrees that conditions associated with a stage of life or a normal physiological process are considered common if they occur in more than one half of those experiencing that stage or process.

In a ruling that will have significant impact on the herb industry, FDA has stated that benign prostatic hyperplasia (BPH) should not be considered a consequence of aging. Even if BPH were considered a direct consequence of aging, claims to treat or prevent it would still be treated as disease claims, because failure to obtain effective treatment can cause significant or permanent harm. Consequently, "Helps to maintain normal urine flow in men over 50 years old," is considered an implied disease claim. The average or normal state in men over 50 years old is diminishing urine flow, in most cases due to BPH, so that the apparent "maintenance" really represents a claim of improvement (treatment).

Examples of allowed claims are shown in Table 1. Disallowed claims are shown in Table 2; these remain disease claims.

#### EFFECTS ON A DISEASE OR DISEASES THROUGH ONE OR MORE OF THE FOLLOWING FACTORS

Name of the Product. The proposed rule argued that a statement would be considered a disease claim if it claimed explicitly or implicitly to have an effect on diseases through one or more factors including the name of the product. Examples include: Carpalum (carpal tunnel syndrome); Raynaudin (Raynaud's phenomenon); Hepatacure (liver problems). Acceptable names suggested were Cardiohealth and Heart Tabs. Under the final rule ads could be called "Heart Tabs" if the claim was to "maintain healthy circulation" or some other role related to the structure/function of the heart that did not imply treatment or prevention of disease. If, however, the product name was not qualified by any further claim on the labeling, the product would be considered as treatment or prevention of cardiovascular disease. The name of a product should not contain the name or recognizable portion of a name of a disease. Also, the name should not use terms such as "cure, treat, correct, prevent" or other terms that suggest treatment or prevention of disease. Thus, Carpalhealth and Circucare would be considered disease claims. "Soothing sleep" could be considered a claim to treat insomnia unless the labeling made clear the product was intended only for occasional sleeplessness. HepataCare and HepataHealth could also be considered disease claims because "Hepata" could be read as a reference to hepatitis unless the labeling made clear that the product was intended for general liver

health and not intended to treat or prevent hepatitis. FDA will issue for public comment a draft guidance to provide clarification and examples of claims and product names that would and would not be considered disease claims under the final rule.

Product Formulation. Listing a dietary ingredient in the ingredient list of a DS will not be considered to imply an effect on disease unless the ingredient is one that has been regulated primarily as a drug and is well-known to consumers for its use or claimed use in preventing and treating a disease. In those cases where a manufacturer does add a drug ingredient to its product that is well-known to treat or prevent disease and label its presence, FDA may consider it a disease claim. This also pertains to a dietary ingredient found in common foods whose biological activity is first characterized in a food context but which is subsequently approved as a drug, i.e., indol-3-carbinol (I3C), a compound discovered in broccoli and other vegetables. The question arises: If I3C were to be approved as a breast cancer drug, would a claim that a vegetable-based DS product contains I3C be permitted as a structure/function claim? Where an ingredient has been approved as a drug, DSHEA prohib its marketing of the ingredient as a DS, unless the ingredient itself was previously marketed as a food (including a DS), or unless a food containing the ingredient was previously marketed for the presence of the ingredient. In this example, the isolated ingredient I3C could not be marketed as a DS unless a food containing I3C had been marketed for the presence of I3C before the drug was approved or was the subject of substantial investigations that had been made public. For purposes of this section, the agency may consider as a disease claim a claim that the product contains an ingredient that has been regulated by FDA as a drug, whether marketed OTC or by prescription, and that is well known for its use in preventing or treating disease. This is the so-called Cholestin(R) "provision" referring to the case of a product composed of Chinese red yeast rice that contains a naturally-occurring compound that has also been approved as a drug, i.e., lovastatin, for the reduction of cholesterol levels.

Table 1: Examples of Allowed Conditions and Statements for which Structure/Function Claims Can Be Made under DSHEA	
Abstentmindedness and mild memory problems associated with aging	Minor muscle pain during exercise
Antispasmodic	Morning sickness associated with pregnancy (rescinded by FDA on Feb. 9, 2000)
Appetite suppressant and weight loss (if no link to obesity)	Noncystic acne
As part of diet to maintain healthy blood sugar levels	Premenstrual syndrome (PMS) and normal, healthy attitude during PMS
Leg edema associated with pregnancy	Support for menopausal women
Treats/prevents nocturnal leg muscle cramps	Presbyopia (inability to change focus from near to far, and vice versa, associated with aging)
Helps support cartilage and joint function	Mild mood changes, cramps and edema associated with the menstrual cycle
Promotion of digestion	Other signs of aging on the skin, e.g., liver spots, spider veins
Maintenance of cholesterol levels that are already within the normal range	Smoking alternative, reduced desire to smoke, mimics oral sensations of cigarette smoke
Hair loss associated with aging	Increases stamina
Hot flashes	Relief of stress and frustration
Immune system function	Tonic
Maintenance of intestinal flora	Wrinkles
Healthy lung function	
Laxative (occasional constipation)	

Citation of Publication Titles. FDA agrees that in enacting DSHEA, Congress intended to encourage the dissemination of scientific research and truthful, non-misleading information. FDA also agrees that consumers can benefit from reviewing the scientific support used to substantiate a statement for a DS. In keeping with these goals, FDA has

modified the law to narrow the circumstances under which citation to a scientific reference will be deemed a disease claim. Citation of a title referring to a disease will be treated as a disease claim if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease. One element that the agency will look at is the prominence of the citation in the labeling. If, for example, the citation is simply listed in the bibliography section of the labeling among other titles, it generally will not suggest an implied disease claim. On the other hand, highlighting, bolding, using large type size or prominent placement of the citation that refers to a disease use in the title could suggest the product has an effect on disease. The agency will also consider whether the cited article provides legitimate support for an SF claim that appears in the labeling of the DS. Enhancing the bibliography with citations to scientific references that refer to a disease in the title that have no reasonable relation to the SF claim will be considered a disease claim. FDA will also consider whether citations are to bonafide research. FDA encourages manufacturers to cite references that provide a balanced discussion of the evidence supporting a SF claim. If specific information about an unlabeled use of a product is requested by a consumer and the request is not solicited by the manufacturer, providing articles that are responsive to the request will not be considered a disease claim.

**Table 2: Examples of Conditions and Statements that Remain Disease Claims; Not Permitted under DSHEA**

Alzheimer's disease and other senile dementia	Glaucoma
Antibiotic	Headache tension
Antiinflammatory	Prevents irregular heart beat
Anticonvulsant	Maintains healthy lungs in smokers
Arteriosclerotic diseases in coronary, cerebral or peripheral blood vessels	Nasal decongestion
Benign prostatic hyperplasia (BPH)	Osteoporosis
Promotes low blood pressure	Maintains normal bone density in post-menopausal women
Bronchodilator	Prohibits bone fragility in post-menopausal women
Relieves crushing chest pain	Inhibits platelet aggregation
Lowers cholesterol	Hyperemesis gravidarum of pregnancy
Chronic constipation	Acute psychosis of pregnancy
Expectorant	Toxemia of pregnancy
Maintains well being during cold and flu season and dietary support during cold and flu season	Severe depression associated with the menstrual cycle
Cystic acne	Deters bacteria from adhering to the wall of the bladder and urinary tract
Decreases effect of alcohol intoxication	Helps maintain normal urine flow in men over 50
Controls blood sugar in persons with insufficient insulin	

In an interesting development affecting supplement manufacturers who fund scientific research on their own products, FDA states that third party literature provisions of DSHEA do not apply to the citation of titles in product labeling, because the third-party literature exemption applies when only when the publication does not promote a particular manufacturer or brand of DS. Therefore, if the reference or the title of the reference was disseminated by a manufacturer of the DS discussed in the reference, FDA concludes that this use promotes the manufacture's brand, and that the third party literature exemption would not apply. Further, such publications must be displayed or presented with other such items to present a balanced view of the available scientific information. A citation to an article alone could not meet these requirements.

Use of "Disease" or "Diseased:" The terms "disease" or "diseased" classify a statement as a disease claim. FDA agrees that general statements about health promotion and disease

prevention may be acceptable as long as the statements do not imply that a specific product can diagnose, mitigate, cure, treat or prevent disease.

**Pictures, Vignettes, and Symbols.** FDA agrees that in most cases a picture of a healthy organ would not be considered a disease claim if the labeling as a whole does not imply treatment or prevention of disease. The heart symbol, however, is widely recognized for disease treatment/prevention, and its use constitutes an implied disease claim. A picture of a healthy EKG tracing is also an implied disease claim. Also, the heart symbol has become so widely associated with the prevention of heart disease that its use in the labeling of DS would ordinarily be considered an implied heart disease prevention claim.

**Membership in Product Class.** Previously, the proposed rule provided examples of "class names" that would imply disease, treatment or prevention and were not allowed. These included the terms antibiotic, laxative, analgesic, antiviral, diuretic, antimicrobial, antiseptic, antidepressant, and vaccine, among others. Acceptable examples included energizer, rejuvenative, revitalizer or adaptogen. Now FDA has decided that claims for relief of occasional constipation are not disease claims; thus, the term "laxative" is not considered a disease claim. The claim "appetite suppressant" is an acceptable SF claim because obesity is a disease, not overweight. An appetite suppressant may be intended for ordinary weight loss, rather than a treatment for obesity. Therefore, such a claim may be appropriate in context. The claim "tonic" is not a disease claim. FDA does not consider the term "antispasmodic" to constitute a disease claim because it is not closely associated with treatment or prevention of gastrointestinal disease. The term "anti-inflammatory" is a disease claim because it is strongly associated with treatment of certain serious gastrointestinal diseases. However, a term considered a substitute for disease therapy would be a disease claim if it explicitly/implicitly claimed that a DS was a substitute for another product that is a therapy for disease. "Herbal Prozac" and "Herb Phen-fen" are examples.

**Augmentation of Therapy or Drug for Disease.** FDA agrees that DS may be useful in providing nutritional support. Associating such statements with an express or implied claim that a DS augments therapy or drug action, however, implies the DS has a role in treating or preventing the disease for which the drug or therapy is used. Example: "Use as part of your diet when taking insulin to help maintain a healthy blood sugar level" is a disease claim.

However, "Use as part of your diet to help maintain a healthy blood sugar level" is acceptable. Deleting the reference to insulin removes the implication that the DS is augmenting the insulin to treat, mitigate, prevent, or cure diabetes. The terms "strengthen, reduce, improve, modify, inhibit, protect" or "defend" may be appropriate terms in some contexts, i.e., when the statements do not suggest disease prevention or treatment use. If however, these terms imply that the DS augments a particular therapy or drug action or suggests an effect on disease, FDA will consider these statements disease claims.

**Role in Body's Response to Disease or Disease Vector.** Under the final proposed regulation, the statements "supports the body's antiviral capabilities" or "supports the

body's ability to resist infection" are disease claims. However, "supports the immune system" is acceptable. A claim that a product supports the body's antiviral capabilities represents a claim of treatment or prevention of a specific class of diseases, those caused by viruses (e.g., colds, hepatitis, or HIV infection) and is therefore not allowed for a DS.

Treatment/Prevention of Adverse Events. Because this final rule uses a different definition of disease than FDA had proposed in its earlier ruling in 1998, this section has been revised to state that claims about adverse events are disease claims only "if the adverse event constitutes disease."

Claims that a product is useful because it counterbalances the effect of a drug in depleting a nutrient or interfering with the metabolism of a nutrient are acceptable SF statements. However, if a claim expressly or implicitly suggests that a DS is intended to augment a specific drug, drug action, or therapy for a disease or serve the same purpose as a specific drug or therapy for a disease, then the statement may be considered a disease claim. Example: "Helps individuals using antibiotics to maintain normal intestinal flora" is a disease claim, but "Helps maintain intestinal flora" is acceptable. Rationale: The statement "helps individuals using antibiotics to maintain normal intestinal flora" does not explicitly refer to a disease, but there is an implicit claim that use of a DS while taking antibiotics will prevent or mitigate a disease. Why? Persons using certain antibiotics are at risk of developing overgrowth in the gut of a genetic organism, because along with fighting the target organism in pathothe body, the antibiotic can suppress normal intestinal flora that are used to prevent infection in the gastrointestinal tract. Thus, in FDA's view, this statement would make an implied disease prevention claim.

Otherwise Affects Disease. Under the final rule, a statement would be a disease claim if it suggests an effect on a disease or class of diseases in a manner other than those specifically set out in the first nine criteria mentioned above. This is the "catch-all" provision. In the comments, FDA was asked to comment on the following statements: "Provides nutritional support for women during premenstruation by promoting proper fluid balances and breast health." "Ginger supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation." These do not appear to FDA to constitute drug claims.

Specific Claims Not Mentioned in the Proposed Rule. FDA allows that some minor pain relief claims may be appropriate SF claims for DS. A claim that a product is intended to treat minor pain without referring to other conditions, symptoms, or parts of the body that would imply disease treatment or prevention would be acceptable SF claims, because minor pain by itself can be caused by a variety of conditions, not all of them disease related. FDA did not, however, agree that general well-being or health maintenance claims would encompass such pain claims. Pain is not a normal state, nor are there "normal pain levels." While the claim to maintain or support joints is appropriate, use of the claim in conjunction with a name that includes the term "pain" renders this a disease claim.

Acceptable SF claims could be made, however, for pain associated with non-disease states (e.g., muscle pain following exercise).

In other areas, FDA said that the statements, "boosts stamina, helps increase muscle size, helps enhance muscle tone" are acceptable SF claims because they do not refer to any disease. "Deters bacteria from adhering to the wall of the bladder and urinary tract" is not acceptable, as it implies prevention of bacterial infection. The claim, "dietary support during the cold and flu season" and "promotes general well-being during the cold and flu season" are disease claims and are not acceptable, i.e., the products will prevent colds or flu or will mitigate the symptoms of those diseases. FDA agrees that certain smoking alternative claims may be acceptable if they do not imply treatment of nicotine addiction. "Smoking alternative," "temporarily reduces your desire to smoke" and "mimics the oral sensations of cigarette smoke" may be acceptable if the context does not imply treatment of nicotine addiction.

**Allowance of Some OTC Drug Claims.** In an important ruling that might result in the blurring of the line between a DS and an OTC drug, FDA agreed that inclusion of a claim in an OTC monograph does not preclude its use as an SF claim; FDA agrees that some OTC drug claims may be acceptable SF claims, but others are disease claims. Examples: Relief of sour stomach and upset stomach (from the OTC antacid monograph) are acceptable SF claims because they refer to nonspecific groups of conditions that are not disease related. Occasional heartburn and occasional acid indigestion can also be considered nonspecific symptoms and therefore appropriate SF claim areas. By contrast, recurrent or persistent heartburn and acid indigestion can be signs of significant illness and are therefore disease claims. "Alleviates the symptoms referred to as gas," "alleviates bloating," "alleviates pressure," "alleviates fullness," and "alleviates stuffed feeling" are all acceptable SF claims (OTC anti-gas monograph). "For the prevention and treatment of the nausea, vomiting and/or dizziness associated with motion" is a permitted SF claim (anti-emetic monograph). "For the relief of occasional sleeplessness" is acceptable (nighttime sleep aid monograph). "Helps you fall asleep if you have difficulty falling asleep," or "helps to reduce difficulty falling asleep" are disease claims as they imply treatment of insomnia, a disease. "Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness" is acceptable (alertness aids monograph) because occasional fatigue and drowsiness are not characteristic symptoms of a specific disease or class of diseases. Chronic fatigue or daytime drowsiness can be symptoms of chronic fatigue syndrome or narcolepsy and are disease claims. "Occasional simple nervous tension," "nervousness due to common, everyday overwork and fatigue," "a relaxed feeling," "calming down and relaxing," "gently sooth away the tension," "calmative," "resolving that irritability that ruins your day," "helps you relax," "restlessness," "nervous irritability," "when you are under occasional stress" and "helps you work relaxed" are all acceptable SF claims, because all suggest occasional rather than long-term or chronic mood changes (daytime sedative monograph). "Nervous tension headache" is a disease claim, because tension headache meets the definition of disease. (See Table 3.)

**Table 3: OTC Drug Monographs Containing Claims  
Now Allowed as Structure/Function Claims under DSHEA**

Antacid  
Antigas  
Anti-emetic (Nausea)  
Aphrodisiacs  
Daytime sedatives (stress, tension)  
Digestive aid  
Laxative  
Nighttime Sleep-aid  
Stimulant  
Stool softener  
Weight control

"Arouses or increases sexual desire and improves sexual performance" is acceptable (aphrodisiacs monograph) because it does not imply treatment of a disease. "Helps restore sexual vigor, potency and performance," "improves performance, staying power and sexual potency," "builds virility and sexual potency" are disease claims because they use the term "potency" which implies treatment of impotence, a disease. If, however, these claims make clear that they are intended solely for increased sexual function associated with aging, they could be acceptable SF claims.

To relieve the symptoms of benign prostatic hypertrophy, e.g., urinary urgency and frequency, "excessive urinating at night and delayed urination" is a disease claim because BPH meets the definition of disease. "Relieves excessive secretions of the nose and eyes" is a disease claim as it refers to the characteristic signs or symptoms of hay fever. "Digestive aid," "stool softener," "weight control" and "menstrual" are, by themselves, acceptable SF claims if the labeling does not otherwise imply treatment or prevention of disease. "Nasal decongestant," "expectorants," and "bronchodilator" are disease claims because nasal decongestant is a treatment for a characteristic symptom of colds, flu, and hay fever; expectorant is a treatment for a characteristic symptom of colds, flu and bronchitis; and bronchodilator is a treatment for bronchospasm, a characteristic symptom of asthma. "Treatment and/or prevention of nocturnal leg muscle cramps, i.e., a condition of localized pain in the lower extremities usually occurring in middle life and beyond with no regular pattern concerning time or severity" is an appropriate SF claim (nocturnal leg muscle cramp monograph). Nocturnal leg cramps do not meet the definition of disease.

Regarding safety of DS making an allowed OTC claim, in a statement that is likely to increasingly obscure the line between a DS and an OTC drug, FDA also noted that in light of the statutory requirement that DS bear all information that is material in light of consequences that may result from use of the product or representations made about it, DS that contain or are labeled as containing ingredients covered by an OTC monograph and that are being sold for the claims covered by the monograph may be misbranded to the extent that they omit material information required under the monograph. That is, information on contraindications or potential adverse side effects required in an OTC drug monograph now appears to be required for a DS label if the product contains an

ingredient approved as an OTC drug and is marketed as a DS for the same indication in the OTC drug monograph. For example, if the OTC monograph required a label statement that products containing a particular ingredient should not be used by a person taking a prescription MAO (monoamine oxidase) inhibitor, a DS containing that ingredient would be misbranded if its label did not include such a statement.

**Substantiation of Claims.** FDA does not believe that the new rule is the appropriate venue to address substantiation requirements. The CDSL included guidance on what quantity and quality of evidence should be used to substantiate SF claims. The commission also provided guidance on the content of the substantiation files for such claims including the 30-day notification letter to FDA, identification of the product ingredients, evidence to substantiate the claim, evidence to substantiate safety, assurances that GMPs were followed, and the qualifications of the persons who reviewed the data on safety and efficacy. FDA has stated that it agrees with the guidance of the commission and encourages DS manufacturers making SF claims to follow this guidance. Contrary studies should be considered when deciding whether to make and how to word a SF claim to assure that any statements made are truthful and not misleading. In a rule that affects the "phytoequivalence" issue of herbal products, FDA says that there is no specific statutory requirement that the studies substantiated in the statement be performed using the actual marketed formulation. However, many ingredients and factors influencing the formulation can affect the safety and effectiveness of the DS. These variations from the marketed product should be considered before using a study to substantiate a claim made for a particular product.

**Structure/Function Claims for Conventional Foods.** A large area of activity in the market has developed in the area of claims for conventional foods, where manufacturers have added herbs and other supplement ingredients to foods and then made SF claims for them. FDA has stated that this rule applies to claims for DS only. FDA advises, however, that for consistency, FDA is likely to interpret the dividing line between SF claims and disease claims in a similar manner for conventional foods as for DS.

**Relationship Between Structure/Function Claims and Health Claims.** Structure/function claims are not a subset of health claims as defined in NLEA. To be a health claim, a claim must refer to the relationship between a food substance and a disease or health-related condition. FDA interprets "health-related condition" to mean a state of health leading to disease. This rule makes clear that only SF claims that do not assert health claims may be made.

**Implementation Plan.** All manufacturers will have 11 months after the effective date of the final rule (February 7, 2000) to come into compliance. Small business will have 17 months after the effective date of the final rule.

## **REFERENCES**

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(3.) 63(82) FR 23623-23632. April 29, 1998. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. [Docket No. 98N-0044].

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